

### REMARKS

Applicants have carefully considered the matters raised by the Examiner in the outstanding Office Action but remain of the position that patentable subject matter is present. Applicants respectfully request reconsideration of the Examiner's position based on the Declaration of Mr. Sikorski, the amendments to the claims and the following remarks.

The present invention is directed to a dried, uncomplexed modified cyclodextrin product and a process for making the same. An aqueous solution of uncomplexed modified cyclodextrin is dried on a drum dryer and recovered to produce an agglomerated uncomplexed modified cyclodextrin product having superior dusting properties and superior dissolution in water properties compared to a conventional spray dried uncomplexed modified cyclodextrin.

In order to further highlight this aspect of the present invention, a declaration of Mr. Sikorski has been provided.

Mr. Sikorski prepared 5 samples of agglomerated cyclodextrin using drum drying and spray drying techniques as illustrated in Examples 1-5 on pages 11-14 of the application. Mr. Sikorski then analyzed each dried sample and determined the particle size distribution and the dissolution rate for the drum dried and spray dried agglomerated cyclodextrin.

The resulting data demonstrates that 50% of the drum dried agglomerated cyclodextrin had a particle size greater than 30 microns while 90% of the spray dried agglomerated cyclodextrin had a particle size less than 30 microns. Furthermore, the dissolution time of the drum dried agglomerated cyclodextrin was about 3 to 10 times faster than the spray dried agglomerated cyclodextrin.

The declaration of Mr. Sikorski demonstrates that a superior dried product is obtained using a drum drying technique as opposed to a conventional spray drying technique. This declaration demonstrates that all drying techniques are not interchangeable if it is desired to achieve the objects of the present invention.

Furthermore, Mr. Sikorski states that such results are surprising and unexpected because he, as one of skill in the art, did not expect such different results between a spray dried uncomplexed modified cyclodextrin and a drum dried uncomplexed modified cyclodextrin.

The Examiner had rejected claims 7-11 as being unpatentable over Shah, in view of Walsh or Giacobello. Claims 12-13 and 15-18 had been rejected as being unpatentable over Majid in view of Shah.

Applicants submit that the present invention is not taught or suggested in Shah, Walsh, Giacobello, or Majid viewed alone or taken in combination. Specifically, none of the cited references teaches that particle size distribution improvements can be made to an agglomerated uncomplexed modified cyclodextrin product by drying a solution of uncomplexed modified cyclodextrin on a drum dryer.

With regard to claim 7, the Examiner had cited Shah for the teaching that a solution of sulfoalkyl ether cyclodextrin can be isolated by a suitable drying technique such as vacuum drum drying.

Shah states that suitable drying techniques such as freeze drying, spray drying, or vacuum drying can be used to dry a sulfoalkyl ether cyclodextrin, see column 3, lines 23-26. Examples 1-5 of Shah describe that drying is conducted using either a Buchi apparatus or freeze drying.

A Buchi apparatus is a laboratory apparatus used to dry materials in a rotating flask by applying a vacuum and heat from a water bath. Typically, the temperature of the water bath is much lower than the temperature of the steam introduced into a drum dryer. Drying conducted on a Buchi apparatus is not similar to drum drying.

Shah does not suggest that there is any difference in the composition of the dried product when using either freeze drying or the Buchi apparatus. Therefore, there is no teaching in Shah that different drying techniques will provide a different composition of dried product. Applicants submit that it is not obvious to one of skill in the art to expect that a superior dried product can be obtained using drum drying in light of the teachings of Shah.

Giacobello states that the drying process can be hastened and further agglomeration of the dried product can be achieved using a drum dryer, see column 10, lines 27-34.

Giacobello, however, dries a slurry or wet cake of a water absorbent composition. In contrast, claim 7 recites that a solution of uncomplexed modified cyclodextrin is dried. The novel results of the present invention are achieved by drying a solution. Giacobello does not suggest that drying a solution yields improved results. Furthermore, Giacobello is drying a water absorbent material. Uncomplexed modified cyclodextrin is not a water absorbent material, it is a water soluble material.

Walsh states that a slurry or paste prepared from beans can be dried in a drum dryer.

Walsh does not dry a solution of uncomplexed modified cyclodextrin. Walsh also does not make the distinction between dried product characteristics obtained by various drying techniques, see column 6, lines 1-5.

Further, Applicants submit that it would not be obvious to combine the teachings of Shah, Giacobello and Walsh since none of the references state that novel results are obtained if a solution is first prepared then dried using a drum dryer. There is no teaching or suggestion that solutions dry better than other compositions and there is no teaching or suggestion that drum dryers dry better than other drying techniques.

With regard to claim 12, the Examiner had cited Majid for the teaching that water can be added to control the size of the agglomerates to achieve the claimed particle size distribution.

Majid is inappropriate for two reasons, first it is directed to a complex while the present invention is directed to uncomplexed modified cyclodextrins; and second the amount of water used in Majid is not enough to form a solution with the complex while the present invention is directed to a solution of uncomplexed modified cyclodextrin.

Cyclodextrin guest complexes are taught in Majid. Majid is not directed to agglomeration of uncomplexed cyclodextrin. In contrast, the present invention is specifically directed to uncomplexed cyclodextrin.

The Examples of Majid demonstrate that cyclodextrin complexes in solid form is agglomerated by the addition of a small amount of water as a binding agent. In contrast, claim 12 recites that the claimed product is obtained by drying a solution of uncomplexed modified cyclodextrin.

Since Majid introduces only a small amount of water as a binding agent rather than forming a solution, there is no teaching or suggestion in Majid to add water in a much greater amount in order to form a solution which would yield the claimed particle size distribution

In light of the above, it is also submitted that claim 12 is patentable over Shah, Giacobello and Walsh taken alone or in combination.

Turning to the remaining portions of the Office Action, claims 7-11 had been rejected as being indefinite. Applicants have herein amended claims 7 and 12 to correct the grammatical errors pointed out by the Examiner as well as additional errors that were noticed.

Specifically, a comma has been inserted after "200 microns" in claim 7. Commas have also been inserted after "dried" appearing two times in claim 7 and two times in claim 12.

As noted by the Examiner, Walsh further teaches that single and double drum dryers are interchangeable in the art. Applicants agree with this teaching and the claims as amended recite the use of a drum dryer rather than a double drum dryer. Support can also be found on page 7, paragraph 2 of the Application where it states that a drum dryer can be used.

The last passage of claim 7 has also been amended to more particularly state the features of the invention. Claim 7 has been amended to recite language similar to that used in claim 12. Claim 7 now recites that the percentage by weight refers to a percentage by weight of "said product", and the particle sizes are "about" the ranges claimed. Support for these amendments can be found in claim 12.

New claim 19, dependent upon claim 7, has also been added to mirror the language contained in claim 13.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance and such action is respectfully requested. Should any extensions of time or fees be necessary to

maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit account #02-2275.

Respectfully submitted,

MUSERLIAN, LUCAS AND MERCANTI, LLP

By: Donald C. Lucas  
Donald C. Lucas, Reg. #31,275  
(Attorney for Applicant)  
600 Third Avenue  
New York, New York 10016  
Tel. # (212) 661-8000

DCL/mr

Encl: Declaration of Chris Sikorski executed September 10, 2003  
Return receipt post-card